Supreme Court, U.S.
FILED
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(2) (3)

Nos. 91-81 and 91-300

In the Supreme Court of the United States

OCTOBER TERM, 1991

BARR LABORATORIES, INC., PETITIONER

v.

LOUIS SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, CROSS-PETITIONER

v.

LOUIS SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION AND CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether a court has equitable discretion to withhold a remedy in an action under 5 U.S.C. 706(1) of the Administrative Procedure Act to "compel agency action unlawfully withheld or unreasonably delayed."

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OPINION BELOW

The opinion of the court of appeals, Pet. App. 1a-9a, is reported at 930 F.2d 72.

JURISDICTION

The judgment of the court of appeals was entered on April 16, 1991. The petition for a writ of certiorari was filed on July 15, 1991. The cross-petition was filed on August 16, 1991. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Under the Food, Drug, and Cosmetic Act (the FDCA or Act), no one may introduce a new drug into interstate commerce without receiving approval of a new drug application from the Food and Drug Administration (FDA). 21 U.S.C. 355(a); 21 C.F.R. 5.10(a)(1). A new drug application must demonstrate the drug's safety and effectiveness and therefore typically includes, among other things, controlled clinical studies of the drug's safety and efficacy. 21 U.S.C. 355(b)(1)(A). Persons who wish to distribute generic drugs, *i.e.*, copies of name-brand drugs already approved by FDA, may file "abbreviated" new drug applications. 21 U.S.C. 355(j). An abbreviated application need not reproduce the types of clinical studies on which approval of the name-brand drug was based. In order to make generic drugs available to the public more quickly and at less expense, abbreviated applications need only demonstrate, in lieu of safety and efficacy studies, that the generic drug is "bioequivalent" to the name-brand drug and that the generic drug is properly manufactured and labeled. 21 U.S.C. 355(j)(2)(A).

The FDCA provides that the FDA "shall approve or disapprove" an abbreviated new drug application "[w]ithin one hundred and eighty days of the initial receipt of an application." 21 U.S.C. 355(j)(4)(A). The FDCA does not specify any consequences that will follow if the FDA fails to act on an application within 180 days. Statutory review "from an order of the [FDA] refusing or withdrawing approval of an application under this section" may be obtained by filing, in the petitioner's circuit of residence or "the United States Court of Appeals for the District of Columbia Circuit * * * a written petition praying that the order of the [FDA] be set aside." 21 U.S.C. 355(h).

2. Petitioner, Barr Laboratories, commercially produces generic drugs. In July 1990, it filed a petition in the District of Columbia Circuit, contending that the FDA had not approved or disapproved, within the 180-day time limit, 21 of its abbreviated new drug applications. Petitioner sought a writ of mandamus to compel the FDA to act upon applications pending beyond the 180-day limit and "adhere to the time limits" with respect to pending applications or applications that may be filed in the future. Pet. App. 24a-25a. See generally *id.* at 10a-25a.

The FDA acknowledged that it had not met the statutory time limits and that a lag between the submission of applications and their approval or disapproval would continue to endure in the near future.[1]

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[1] As the court of appeals noted, the FDA "explain[ed] the lag as the product of a personnel crisis that began in the summer of 1988, when scandal beset its generic drug division, forcing out some employees and diverting others from their usual work." Pet. App. 3a.

Therefore, as the court of appeals noted, the question before the court was "not whether the [FDA] has violated a statutory mandate—it has—but whether [to] exercise [the court's] equitable powers to enforce the deadline." Pet. App. 4a.

To determine whether to exercise its equitable powers, the court considered a number of factors first identified in *Telecommunications Research & Action Center* v. *FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) (*TRAC*).[2] While acknowledging the importance of getting useful drugs into the public's hands as quickly and cheaply as possible, the court emphasized that petitioner had not been singled out for mistreatment by the FDA, and that such delays are endemic in the agency's current circumstances, endured by all drug manufacturers seeking approval for abbreviated drug applications. Pet. App. 4a-6a. Granting the requested relief, the court explained, would do no more than place petitioner at the front of a very long line of similarly situated drug manufacturers: "[A] judicial order

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[2] The six factors identified in *TRAC*, 750 F.2d at 80 (citations and internal punctuation omitted), are as follows:

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

putting Barr at the head of the queue simply moves all others back one space and produces no net gain [for the public]." *Id.* at 6a. Thus, because the requested relief would only advance petitioner's own economic interests, would not advance "the cause of equal treatment," *ibid.*, or any of the policy objectives Congress sought to achieve in establishing the abbreviated drug application system, and would interfere with the FDA's ability to achieve other congressional goals, the court declined to issue a writ of mandamus. *Id.* at 7a.

ARGUMENT

1. Petitioner does not seek review of the court of appeals' conclusion that the relief requested would be inconsistent with principles of equity. The sole argument in its petition for a writ of certiorari is that although equitable discretion may govern the issuance of a writ of mandamus, a court lacks equitable discretion under the judicial review provisions of the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq.*, and that the court of appeals was therefore obliged to direct the FDA to act on petitioner's applications within the 180-day limit, no matter how inequitable that result may be. Pet. 11. That question does not warrant review by this Court, for several reasons.

a. Petitioner did not raise in the court of appeals the question presented in the certiorari petition, and the court of appeals did not pass on that question. Petitioner filed this action as an original action in the court of appeals, and the only relief sought by petitioner in that court was a writ of mandamus. The petition filed in the D.C. Circuit by petitioner made that point expressly: "The appropriate remedy for such agency inaction is a writ of mandamus issuing from this Court." Pet. App. 24a. Petitioner did

not claim that it was entitled to an injunction as a matter of law if the court of appeals determined that the FDA had violated the abbreviated new drug application provisions of the FDCA.

Petitioner maintains that it raised this claim in the court of appeals because petitioner contended below that the court of appeals had jurisdiction over this action under the APA. In this regard, petitioner claims that it "sought relief under the APA as well as the All Writs Act, App. 11a (Pet. ¶ 1), but the Court of Appeals treated the two grounds as if they were identical." Pet. 7. That allegation, however, was not sufficient to preserve the claim that petitioner has presented in the certiorari petition. Even if petitioner were correct that the APA provided the court of appeals with jurisdiction over this case, but see page 8, *infra*, that claim does not raise the question that petitioner has asked this Court to review: namely, whether the APA's judicial review provisions divest the courts of the equitable discretion they would otherwise enjoy to grant or withhold relief to compel agency action that is unreasonably delayed.[3]

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[3] Moreover, while petitioner now maintains that the APA supplies a party with a basis for relief that is distinct from the relief available under the All Writs Act, 28 U.S.C. 1651, in the court of appeals petitioner merged the two theories. The only express mention of the APA's judicial review provisions in petitioner's papers in the court below came in a context implying that there are no fundamental differences between relief under Section 706(1) and under the All Writs Act, 28 U.S.C. 1651. See Pet. App. 24a ("FDA's failure to act on [applications] filed by [petitioner] effectively has thwarted this Court's jurisdiction. * * * The appropriate remedy for such agency inaction is a writ of mandamus issuing from this Court. 5 U.S.C. § 706; 28 U.S.C. § 1651; *see Telecommunications Research and Action Center v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984).").

This Court has frequently held that "[o]nly in exceptional cases will this Court review a question not raised in the court below." *Lawn* v. *United States*, 355 U.S. 339, 362 n.16 (1958). There are no exceptional circumstances present here. Accordingly, further review is unwarranted.

b. Moreover, there is no conflict among the circuits on the question presented by petitioner. Indeed, not only did the court of appeals not decide that question in this case, no court at any level appears to have addressed the question whether the courts have more, less, or the same degree of equitable discretion to withhold a remedy under the judicial review provisions of the APA than they possess under the All Writs Act (or under the Mandamus Act, 28 U.S.C. 1361). There is no need whatsoever for this Court to address that novel issue in the first instance.

Petitioner contends that *Association of Am. Railroads* v. *Costle*, 562 F.2d 1310 (D.C. Cir. 1977), held "by implication" that "where a finding of unlawful witholding has been made, relief under the APA is required." Pet. 8. An allegation of an intra-circuit conflict, however, is a matter for the court of appeals, not this Court, to resolve. *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957). In any event, *Association of Am. Railroads* does not support petitioner's claim. That case merely compels agency action without discussing whether in an appropriate case equitable considerations could warrant withholding injunctive relief. 562 F.2d at 1321-1322.[4]

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[4] In a different section of the opinion, *Association of Am. Railroads* in fact suggests that an injunction would not have to issue as a matter of law without regard to equitable factors: "The courts are, of course, concerned with the consequences of the decisions which they render; they will examine these

c. In addition, the judicial review provisions of the APA do not apply in the posture of this case. Accordingly, the question presented in the certiorari petition would not be properly before this Court even if petitioner had raised that question in the court below.

As we have noted, Congress provided for judicial review of "an order of the [FDA] refusing or withdrawing approval of [a new drug] application," 21 U.S.C. 355(h). Even if the judicial review provisions of the APA apply to review from an FDA order refusing or withdrawing approval of a new drug application, petitioner has not sought review of such an order. Instead, petitioner seeks judicial review of the FDA's pre-order delay. The D.C. Circuit's decision in *TRAC* analyzes the jurisdictional questions peculiar to claims concerning agency delay when judicial review of final agency action is committed in the first instance to the court of appeals. The *TRAC* decision also explains why the review provisions implicit in the All Writs Act, not the APA, govern cases in this posture.[5]

First, *TRAC* noted that the APA "unquestionably does not confer an independent grant of jurisdiction," 750 F.2d at 76; instead it grants parties a cause of action. See also *Califano* v. *Sanders*, 430 U.S. 99

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consequences as a factor in determining whether to grant the relief requested by the complaining party in a particular case." 562 F.2d at 1319. The court also believed that it had the power to be flexible regarding the date that the court could set for compliance with its mandate. *Id.* at 1321-1322.

[5] *TRAC* noted that the prior decisions of the D.C. Circuit had been "somewhat inconsistent and may be confusing for litigants" concerning the jurisdiction over interlocutory appeals from agency action. 750 F.2d at 74.

(1977). Second, in *TRAC*, as in this case, judicial review of agency action was committed originally and exclusively to the court of appeals. But since "a statute which vests jurisdiction in a particular court cuts off original jurisdiction in other courts in all cases covered by that statute," 750 F.2d at 77, the statute that generally grants district courts jurisdiction over claims as to which the APA supplies a cause of action for adverse agency action, 28 U.S.C. 1331, does not provide a jurisdictional predicate for APA review, because review lies in the courts of appeals. Third, in *TRAC*, as in this case, the statutory jurisdiction is limited. 750 F.2d at 74. In the statutory scheme at issue in *TRAC*, jurisdiction extended only to "final agency action." But in a challenge to agency action unreasonably delayed "there is no final order—indeed, the lack of a final order is the very gravamen of the petitioners' complaint." *Id.* at 75. Therefore, in *TRAC*, as in this case, there is no general jurisdictional basis for review of claims of agency delay.

As noted in *TRAC*, however, the absence of a general jurisdictional basis does not mean that the court lacks power to review petitioner's claim. Under the All Writs Act, the courts of appeals "may issue all writs necessary or appropriate in aid of their respective jurisdictions." 28 U.S.C. 1651. It is well established that the All Writs Act "empowers a federal court to issue writs of mandamus necessary to protect its prospective jurisdiction." *TRAC*, 750 F.2d at 76. *TRAC* therefore held that since agency delay might defeat the court's obligation to review agency decisions on the merits, the All Writs Act authorized the court of appeals to review claims of agency delay

and, in appropriate circumstances, to issue a writ of mandamus to compel agency action.[6]

The reasoning of *TRAC* supports review by the court of appeals of petitioner's claims. The court of appeals has prospective jurisdiction over the FDA's approval or disapproval of petitioner's abbreviated applications under 21 U.S.C. 355(h). The All Writs Act empowers the court to protect that prospective jurisdiction, but confines a court's authority to "all writs necessary or appropriate." Thus, because a writ of mandamus is equitable in nature, the right to a remedy by issuance of that writ is subject to the sound equitable discretion of the court. Otherwise, the writ would cease to be a writ of mandamus. In sum, where judicial review of final agency action lies initially in a court of appeals, a claim of unreasonable agency delay is reviewed under the All Writs Act, not the APA. Thus, the question presented by petitioner —whether a court has discretion under the APA to

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[6] Under the *TRAC* analysis, it makes no difference, for jurisdictional purposes, whether the claim of agency delay is based upon an express statutory deadline or upon an implicit obligation to complete final action within a reasonable amount of time. *TRAC* holds that in assessing the factors that bear upon whether a court should issue a writ of mandamus, a statutorily established deadline "may supply content for [a court-determined] rule of reason." 750 F.2d 80. But the presence or absence of a statutory "deadline" does not provide a jurisdictional basis for review apart from the All Writs Act. Accordingly, for purposes of determining whether judicial review of petitioner's claim is under the APA or the All Writs Act, petitioner does not advance its case by contending that the presence of a statutory deadline converts this from an "unreasonably delayed" action into an "unlawfully withheld" action. 5 U.S.C. 706(1). In either case, FDA delays are reviewable only under the All Writs Act.

refuse to compel agency action unreasonably delayed —has no bearing on the correctness of the court of appeals' decision in this case.[7]

d. In any event, even if the APA judicial review provisions applied to this case, the court of appeals' decision would be correct. The APA provides that a court "shall * * * compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. 706(1). Relying upon the use of the word "shall" in that statute, petitioner argues that the statute was intended to alter the available scope of judicial review of claims of agency delay by eliminating the discretion that courts traditionally possess to withhold an equitable remedy. But even if that term were read as mandatory, courts would be obliged to compel action only for those delays that are "unreasonabl[e]," and that term can be fairly read to embrace the kinds of equitable considerations taken into account by courts in determining whether to issue a writ of mandamus.

This reading is strongly supported by the APA's legislative history. Although Congress did not directly address the scope of a court's discretion under Section 706(1), the House and Senate Committees, and individual congressmen, consistently stated that 5 U.S.C. 706(1) was intended as a "restatement of the scope of review" then existing. S. Doc. No. 248, 79th Cong., 2d Sess. 39 (1946); *id.* at 84 ("[W]e do

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[7] That question could properly be presented in any action seeking to compel agency action unreasonably delayed in which jurisdiction lay originally in the district court. For example, review of some categories of final FDA action is not committed to the courts of appeal. There, jurisdiction lies in the district courts under 28 U.S.C. 1331. See, *e.g.*, *Cutler* v. *Hayes*, 818 F.2d 879, 887 n.61 (D.C. Cir. 1987). In such a case, the APA's judicial review provisions would govern the relief available.

not believe the principle of review or the extent of review can or should be greatly altered. * * * [T]he scope of review should be as it now is.") (remarks of Rep. McFarland); *id.* at 224 ("[The APA] restates the law governing judicial review of administrative action."); *id.* at 278 (interested parties have a right to "compel agencies to act where they *improvidently* refuse to act.") (emphasis added). In response to a request by Congress for comments on the bill prior to passage of the APA, the Attorney General, referring to 5 U.S.C. 706(1), stated that "[t]his section, in general, declares the existing law concerning judicial review." S. Doc. No. 248, *supra*, at 229. As the Attorney General explained, *id.* at 415:

> Section 10 as to judicial review does not * * * make any real changes in existing law. * * * It is an attempt to restate in exact statutory language the doctrine of judicial review as expounded in various statutes and as interpreted by the Supreme Court. I know that some agencies are quite concerned * * * that it will change the existing doctrine of judicial review * * *. I feel sure that should this section be given the interpretation which is intended, namely, that it is merely a restatement of existing law, there should be no difficulty for any agency.[8]

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[8] Because of the substantial role the Department of Justice played in aiding Congress's consideration of the APA, significance attaches to a Department memorandum furnished by the Attorney General. See also *Attorney General's Manual on the Administrative Procedure Act* 108 (1947 & photo reprint 1979) ("[The clause] authorizing a reviewing court to 'compel agency action unlawfully withheld or unreasonably delayed', appears to be a particularized restatement of existing judicial practice under section 262 of the Judicial Code (28 U.S.C. 377). *Safeway Stores, Inc.* v. *Brown*, 138 F.2d 278

Because the APA was intended to restate the existing law concerning judicial review, 5 U.S.C. 706(1) may not be construed as fundamentally altering the scope of review of claims of agency delay. But, at the time the APA was enacted, review of claims of agency delay was available only upon petition for a writ of mandamus.[9] Therefore, courts possess the same discretion under 5 U.S.C. 706(1) to withhold a remedy, when relevant considerations would render the relief inequitable, as they would in entertaining a petition for a writ of mandamus.

Relying upon *Sierra Club* v. *Thomas*, 828 F.2d 783, 793 (D.C. Cir. 1987), petitioner argues that when "a statutory mandate has been violated, the agency action has been 'unlawfully withheld' * * * [and only] in the absence of a statutory deadline does the 'unreasonable delay' test come into play." Pet. 10. Petitioner apparently contends that one test is appropriate for "unreasonably delayed" cases and another for "unlawfully withheld" cases. But petitioner has misread *Sierra Club*. That case gave as an example of action unlawfully withheld for APA purposes, not missing a statutory deadline, but agency recalcitrance in the face of statutory provisions "that require an agency to take specific action when certain preconditions have been met," *i.e.*, failing to perform a specifically mandated duty. 828 F.2d at 793. By con-

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(E.C.A., 1943)."). The decision in *Safeway Stores* concerned claims of agency delay under the Emergency Price Control Act. Final orders were subject to review in the courts of appeals. *Safeway Stores* held that, under the All Writs Act, such claims might be reviewed in a petition for a writ of mandamus.

[9] See, *e.g.*, *Safeway Stores, Inc.* v. *Brown*, 138 F.2d 278 (Emer. Ct. App.), cert. denied, 320 U.S. 797 (1943).

trast, as *Sierra Club* clearly states, "[w]hat differentiates 'unreasonable delay' from 'unacknowledged final action' [which constitutes action that has been unlawfully withheld for APA purposes] is that the petitioner who pleads the former concedes that the agency is still analyzing the matter, but complains that the process is taking too long." *Id.* at 794. Petitioner does not contend that the FDA's delay is a de facto denial of their application or, for some other reason, amounts to "unacknowledged final action." Its complaint throughout has been that the review process is taking too long.[10]

In any event, the "unlawfully withheld" provision of the APA "means that the court *may* compel the agency to act where it has 'unlawfully withheld' action," not that it must. S. Doc. No. 248, *supra*, at 40 (emphasis added). That provision no more withdraws equitable discretion from the courts than does the APA's "unreasonably delayed" provision.

2. Cross-petitioner seeks review of the court of appeals' decision that petitioner was not entitled to a writ of mandamus. The cross-petition was not filed until August 16, 1991, however, and therefore is untimely as a certiorari petition. The cross-petition is timely only by virtue of this Court's Rule 12.3 and therefore should be denied without further consideration if the petition is denied. Sup. Ct. R. 13.5.

In any event, the cross-petition should be denied even if the petition were granted. The balancing conducted by the court of appeals is fact-bound; it is limited to the present posture of this case, Pet. App. 9a ("We thus dismiss the suit, but invite [petitioner]

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[10] Petitioner also relies on *Environmental Defense Fund, Inc.* v. *Costle*, 657 F.2d 275 (D.C. Cir. 1981), but that case did not decide the question presented here.

to refile should circumstances arise that would change the outcome of our analysis."); and it is correct, for the reasons given by that court. Cross-petitioner has identified no aspect of that decision warranting this Court's review.

There is also no merit to cross-petitioner's claim that the decision below conflicts with *Soler* v. *Scott*, No. 89-16051 (9th Cir. Aug. 1, 1991). That case held that a time limit established by the Immigration Reform and Control Act of 1986 was mandatory, not hortatory. Cross-Pet. App. 11a. *Soler* does not address, as does the decision below, whether equitable considerations warrant withholding a remedy for a violation of a statutory deadline.

CONCLUSION

The petition and cross-petition for a writ of certiorari should be denied.

Respectfully submitted.

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SEPTEMBER 1991

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